March 1, 1993

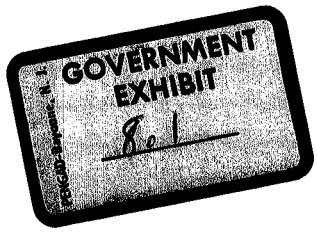
To: H. Pietraszek

Re: <u>Contingency Planning</u>

As part of our Impact Goals, Alan Mackenzie and I have Goals to prepare contingency plans for TAP on the likely changes coming in Healthcare.

Attached is Alan's report "Adverse Medicare Reimbursement Changes" that focuses on the sales related issues; and my report that quantifies the financial impact on TAP of what we most likely feel could happen now. We know more is coming and will update these reports as things develop.

John Rancourt
Alan Mackenzie

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March 1, 1993

Adverse Medicare Reimbursement Changes Contingency Plan for TAP Pharmaceuticals

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With contributions from:
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Jeff Peterson

****CONFIDENTIAL****

Scenario 1

HCFA lowers allowables for drugs that currently are reimbursed under the Medicare Part B provision for non self administered drugs provided incident to physician's service.

Background

The Medicare Physician Payment Reform Act (OBRA 89), was made law and enacted January 1, 1992. Payment for drugs reimbursed by Medicare was included in this legislation. HCFA stated that effective 1/1/92, drugs are to be reimbursed at the lower of estimated acquisition cost or AWP. However, when HCFA published its specific instructions to the state Medicare carriers, it left blank the section on how to calculate estimated acquisition cost. When questioned by the states on this lack of instruction, HCFA responded by saying that it was conducting surveys on true physician cost for drugs and would be specific on how to calculate these allowables after the surveys were completed. In the meantime, HCFA told the states to default to previous payment methodologies, thus most states continue to reimburse at AWP or higher in some states (NC, FL, CA) and only less than AWP in one state, Tennessee (cost + 10%).

Since 1/1/92, HCFA, via the Office of the Inspector General (OIG), has been active in auditing actual oncology practices for acquisition costs of high volume and/or high cost drugs currently paid for by Medicare. In surveying these chemotherapy drugs, OIG has found physician acquisition costs to be significantly below AWP. Discounts of 10% - 40% below AWP were cited.

In addition, the OIG recently published findings of a similar audit on Epogen (Erythropoeitin, Amgen) and found these acquisition costs below AWP. In the case of the chemotherapy study, OIG recommended allowables to be set at some level below AWP. In the Epogen study, OIG specificially recommended an allowable which is 17% below AWP. Lupron currently is sold to physicians for 25% below AWP.

This leads us to believe that HCFA is getting near to resetting drug allowables. It would seem likely that HCFA would use AWP minus some percentage, as this would be much easier to implement versus cost of drug plus some percentage.

From a timing perspective, we've not been able to ascertain when they would implement. The act is already law, this would only be clarifying and enforcing what's in place.

Implications to TAP

Should Lupron allowables be reduced we would be facing a narrower spread between what a doctor buys the product for and his reimbursement. Lupron profits would be less and even worse, if the 20% patient portion was not collected, the physician would lose money on Lupron.

If we use the OIG recommendation on Epogen as an example (AWP - 17%), a physician would purchase Lupron at $350.00 and be reimbursed $363.00 if he collects the full 20% share from the patient. Should the 20% patient co-pay not be paid, the physician would only be reimbursed

$290.50, thus losing $59.50 per vial. For patients without secondary insurance (Medigap) the 20% out of pocket of $72.60 every month will be steep. The physician pressure to collect this 20% will be greater so that he can continue positive revenue flow from using Lupron. While we know most patients (79%) have secondary insurance coverage, the perceived potential loss of money by the physician will have to be dealt with.

Our 1993 plan includes $353 MM of 7.5 mg sales of which we estimate 62% is paid for by Medicare. Any contingency has to deal with a safety net for physicians so that it's impossible for them to lose money (our current situation) and also has to maximize all available reimbursements to continue a positive physician cash flow with the use of Lupron.

Possible Contingency Programs for Scenario 1:

1) **Medigap Assistance Program**

With successful collections of patient co-pays becoming critical, Medigap insurance for Lupron patients will insure the physician complete reimbursement of the set allowables. This program would include:

- Thorough training of TAP field organization of Medigap insurance policies so that they can help offices screen for these secondary policies.

- Information or agreements with suppliers of Medigap policies to assist patients in acquiring Medigap policies. For example, in Illinois a 67 year old Medicare recipient would pay $71.00 per month for an AARP policy that would pay all part A & part B patient co-pays. I'm exploring the legality of TAP providing financial assistance to those patients who may need help in purchasing such policies.

If all Lupron patients had Medigap policies we could insure physicians a minimum positive cash flow of $13.00 per patient/month plus office visit and injection fee.

2) **Quantity Discount Program**

To restore the spread between physician acquisition cost and reimbursed cost we could selectively lower purchase price through quantity discount. We cannot lower catalog price at all because this would lower AWP and reimbursement levels.

For example, if reimbursement levels are reduced to AWP - 17% the numbers would look like this for 1 patient/month:

Physician receives	$363.00 ($290.50 from Medicare, $72.50 from patient)
Physician cost	$350.00
Return	$13.00

We can boost the physician return by lowering his cost via a deal. For example, if we offered a quantity discount of 10% for purchases of 12 units or greater, the numbers now look like this:

Physician receives	$363.00 ($290.50 from Medicare, $72.50 from patient)
Physician cost	$315.00
Return	$48.00

Legally we are supposed to inform any customer that it is their responsibility to pass along discounts to Medicare/Medicaid. Once we've fulfilled our duty to inform, the ball is in the doctor's court on what to bill.

This contingency option is easy to implement, easy to terminate, can protect physician from loss, maximizes physician return and can be selectively applied (by customer class, by purchase volume, etc.). The downside is the effect on AUP, although if it could drive up or protect volume it should be considered.

3) **Flexible Physician Terms Program**

In an effort to further protect physicians' financial interest we could alter our terms of payment from the current "net 90 days". New terms could read "net 90 days or upon complete receipt of 3rd party payment, not to exceed 150 days".

This would provide an additional safety net to physicians who may need additional time to collect secondary insurance. We need to keep in mind that Medigap coverage cannot be filed for until Medicare pays it's share, then the secondary claim is submitted.

Downside here is the effect on DSO, although my guess is that this program would look good to the physicians and their billing people but rarely taken advantage of (like our current Insurance Guarantee Program).

4) **Formal Indigent Program**

Higher dependence on patient co-pays (those without Medigap) could force out patients who were unable to pay $75 - $100 per month out of pocket for Lupron, injection fee and doctor's visit co-pays. We could offer a formal program that would provide financial assistance to patients who's income and assets meet need requirements.

This certainly would provide a safety net for patients, keeping them on the drug, and also make us look good in the doctors' eyes. However, this probably would be costly and cumbersome to administer. We don't view this as a primary option but present it for future discussion.

Discussion

Tennessee serves as an excellent model for this scenario, as their Medicare allowable has been reduced to cost + 10% since March of 1991. Since that time 10% - 20% discounts have been offered to Tennessee Urologists via free goods to provide a safety net. The attached exhibit shows that Uro/Onc unit sales have tracked closely with the rest of the nation in percentage growth.

Scenario 2

HCFA demands drug rebates for Medicare paid for products similar to current Medicaid program.

Background

Since 1/1/91 drug manufacturers who wish to have their products paid for by Medicaid have paid rebates to each state's program, based off a formula involving Average Manufacturers Price, best price to other customers and minimum levels of rebates. Since 1/1/93, drug manufacturers who wish to do business with governmental agencies have had to offer deep discounts calculated by a similar method as the Medicaid formula. As a result TAP now discounts or rebates roughly $100.00 for every 7.5 mg kit sold to Medicaid, V.A., Dept. of Defense hospitals, Public Health service and all non-federal hospitals.

The only government payer of drugs not yet receiving discounts or rebates from manufacturers is Medicare. There have already been discussions on the floor of the House to include Medicare reimbursed drugs into these programs. The Medicaid etc. agreements are saving the government billions of dollars and we must consider the possibility (eventuality?) of this being applied to Medicare.

There is no well defined initiative or pending bill, but this would be an easy and popular tag-on to any other legislation.

Implications to TAP

John Rancourt will be providing detailed financials on this scenario. With a 1 MM unit plan for 7.5 mg in 1993 and our estimate that Medicare pays for at least 62% of that (620,000 units) you can see that a $70 - $100 per unit rebate creates a staggering hit to the bottom line.

TAP 2068751

Possible Contingency Programs for Scenario 2:

1) **Pricing scheme to minimize future rebates to HCFA.**

Under separate cover, Jeff Peterson will provide a detailed report on how current government rebates and discounts are calculated. All of those calculations involve Average Manufacturers Price (AMP) which is a variation of Average Selling Price and minimum discounts off of AMP.

7.5 mg Example	AMP	=	$340.00
	16% Minimum Discount	=	54.40
	Government Price	=	285.60
	$350.00 - 285.60	=	64.40/Vial Rebate

Our current rebates actually are roughly $100 per vial because we have prices to other customers that are below the minimum government price which we must then give to the Medicaid system.

To be properly positioned for Medicare rebates we propose the following:

- No contracts that lower 7.5 AMP.
- If needed, use 3.75 as pricing tool for large customers (Kaiser, HIP, etc.).
- No price to any customer below maximum government price.
- Price increases at CPI at most frequently allowed intervals.

In addition to the above pricing recommendations, we would recommend a major campaign with the physicians on how TAP is playing a significant role in reducing Medicare expenditures. We believe that under this scenario we could grow 7.5 unit sales faster than current LRP because of the decreased "cost to the system".

Discussion

We are fortunate to have different product sizes in our two markets. This gives us a lot more pricing flexibility in 3.75 mg which may be able to use to keep our contracted 7.5 mg price high with important large customers. 3.75 mg sales would not be impacted by any Medicare events as there are essentially no Gyn patients paid for by Medicare.